DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 18, 2014

Spineology, Incorporated
Mr. Tim Crabtree
Regulatory Affairs Manager
7800 3rd Street North
Saint Paul, Minnesota 55128

Re: K143403
Trade/Device Name: Threshold™ Pedicular Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: December 1, 2014
Received: December 2, 2014

Dear Mr. Crabtree:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143403

Device Name
Threshold™ Pedicular FixationSystem

Indications for Use *(Describe)*

The Spineology Threshold™ Pedicular Fixation System is intended for posterior, non-cervical fixation as an adjunct to fusion in skeletally mature patients for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis; trauma, (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and/or failed previous fusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

I. SUBMITTER

Spineology Inc.
7800 3rd Street N.
Saint Paul, MN 55128

Phone: 651.256.8534
Fax: 651.256.8505

Contact Person: Tim Crabtree
Date Prepared: November 24, 2014

II. DEVICE

Name of Device: Threshold™ Pedicular Fixation System
Common Name or usual name: Pedicle Screw System
Classification Name: Orthosis, Spinal pedicle Fixation (21 CFR §888.3070)
Regulatory Class: Class III
Product Code: NKB, MNI, MNH

III. PREDICATE DEVICE

Primary Predicate - Spineology Fortress™ Pedicle Screw System (K140010)

IV. DEVICE DESCRIPTION

The Spineology Threshold ™ Pedicular Fixation System is an addition to Spineology's Fortress pedicle screw family. The Threshold System consists of cannulated titanium screws and rods to allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. The system is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine. The devices are provided sterile. The associated instruments are provided non-sterile.

V. INDICATIONS FOR USE

The Spineology Threshold Pedicular Fixation System is intended for posterior, non-cervical fixation as an adjunct to fusion in skeletally mature patients for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis; trauma, (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and/or failed previous fusion.

VI. COMPARISON OF TECNOLOGICAL FEATURES WITH THE PREDICATE DEVICE

The Spineology Threshold Pedicular Fixation System shares the same indications, materials, design, function, and performance as the Spineology Fortress Pedicle Screw System. The Threshold pedicle screws are cannulated whereas the Fortress pedicle screws are not. The Threshold rods are made of titanium alloy and are 5.5mm in diameter; the Fortress rods are made of cobalt-chrome alloy and are 4.75mm in diameter.

VII. PERFORMANCE DATA

Static testing was performed to verify the design and demonstrate that the Threshold Pedicular Fixation System is substantially equivalent to the Fortress Pedicle Screw System. The performance testing included static compression loading in accordance with ASTM F1717.

VIII. CONCLUSIUONS

The Threshold Pedicular Fixation System is substantially equivalent to the predicate Fortress Pedicle Screw System. This is based on intended use, materials, technological features, and comparative performance testing.